



DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures

The United States Patent and Trademark Office (USPTO) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites comment on this information collection renewal, which helps the USPTO assess the impact of its information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the ***Federal Register*** on June 7, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: United States Patent and Trademark Office, Department of Commerce.

Title: Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

OMB Control Number: 0651-0024.

Needs and Uses: Patent applications that contain nucleotide and/or amino acid sequence disclosures falling within the definitions of 37 CFR 1.821(a) (for applications filed on or before June 30, 2022) or 37 CFR 1.831 (for applications filed on or after July 1, 2022) must include, as a separate part of the disclosure, a copy of the sequence listing in

accordance with the requirements in 37 CFR 1.821–1.825 or 37 CFR 1.831-1.835, respectively. Applicants may submit sequence listings for both U.S. and international biotechnology patent applications. Submissions of sequence listings in international applications are governed by Patent Cooperation Treaty (PCT) Rules 5.2 and 13~~ter~~, as well as the PCT Administrative Instructions, Annex C. The USPTO uses applicants' sequence listings during the examination process to determine the patentability of the claimed invention. The USPTO also uses sequence listings for pre-grant publication of patent applications and publication of issued patents. Sequence listings are publicly searchable after publication of the pre-grant application or issued patent.

This information collection covers the submission of sequence listing information itself. Information pertaining to the initial filing of U.S. patent applications is collected under OMB Control Number 0651-0032 and information pertaining to the initial filing of international applications is collected under OMB Control Number 0651-0021.

Sequence listings in applications filed on or before June 30, 2022 may be submitted via the USPTO patent electronic filing system as an ASCII text file or as a Portable Document Format (PDF) file. For U.S. applications filed on or before June 30, 2022, 37 CFR 1.821(c) permits all modes of submission: paper, read-only optical disc, or electronic filing via the USPTO patent electronic filing system. Sequence listings for international applications may only be submitted on paper or through the USPTO patent electronic filing system. Sequence listings that are too large to be filed electronically through the USPTO patent electronic filing system may be submitted on read-only optical disc.

This information collection also accounts for the requirement under 37 CFR 1.821(e)(1) or 1.821(e)(2) that a copy of the sequence listing submitted pursuant to 37 CFR 1.821(c)(2) or (c)(3) must also be submitted in computer readable form (CRF) in accordance with 37 CFR 1.824. Under 37 CFR 1.821(e)(1) or 1.821(e)(2), applicants who

submit their sequence listings on paper or as a PDF via the USPTO patent electronic filing system must submit a copy of the sequence listing in CRF with a statement indicating that the CRF copy of the sequence listing is identical to the paper or PDF copy provided under 37 CFR 1.821(c)(3) or 1.821(c)(2), respectively. Applicants may submit the CRF copy of the sequence listing to the USPTO via the USPTO patent electronic filing system, or on read-only optical disc or other acceptable media as provided in 37 CFR 1.824. If a new application is filed via the USPTO patent electronic filing system with an ASCII text file sequence listing that complies with the requirements of 37 CFR 1.824(a)(1)–(5) and (b), and the applicant has not filed a sequence listing on paper or as a PDF file, no separate text file is required. Therefore, no associated statement regarding both copies being identical would be required. Similarly, if a new application is filed with an ASCII text file sequence listing on read-only optical disc that complies with the requirements of 37 CFR 1.824(a)(1)–(5) and 37 CFR 1.52(e), the single read-only optical disc is the CRF, and no additional submission is required.

Sequence listings in applications filed on or after July 1, 2022 must be submitted in XML format per 37 CFR 1.831, which was recently implemented to achieve alignment with World Intellectual Property Office Standard ST.26 (WIPO Standard ST.26) (Standard for Presentation of Nucleotide and Amino Acid Sequence Listings Using eXtensible Markup Language (XML) in Patent Applications To Implement WIPO Standard ST.26; Incorporation by Reference, 87 FR 30806, 5/20/22, effective July 1, 2022). These submissions may be made electronically via the USPTO patent electronic filing system as an XML file not exceeding 100MB without file compression, or as an XML file on a read-only optical disc in accordance with 37 CFR 1.834(b)–(c).

One item, Request for Transfer of a Computer Readable Form under 37 CFR 1.821(e), has been removed from this information collection. This item is no longer part of this information collection's process per a recent rulemaking (Electronic Submission of

a Sequence Listing, a Large Table, or a Computer Program Listing Appendix in Patent Applications; 86 FR 57035, 10/14/2021, effective November 15, 2021).

Form Number(s): None.

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated Number of Annual Respondents: 9,550 respondents.

Estimated Number of Annual Responses: 28,550 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately 6 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 171,300 hours.

Estimated Total Annual Respondent Non-Hourly Cost Burden: \$1,483,936.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Commerce, USPTO information collections currently under review by OMB.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the information collection or the OMB Control Number 0651–0024.

Further information can be obtained by:

- E-mail: InformationCollection@uspto.gov. Include “0651-0024 information request” in the subject line of the message.
- Mail: Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Justin Isaac,

Acting Information Collections Officer,

Office of the Chief Administrative Officer,

United States Patent and Trademark Office.

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